NTP
National Toxicology Program

Proposed Review Process for the Report on Carcinogens

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Listening Session

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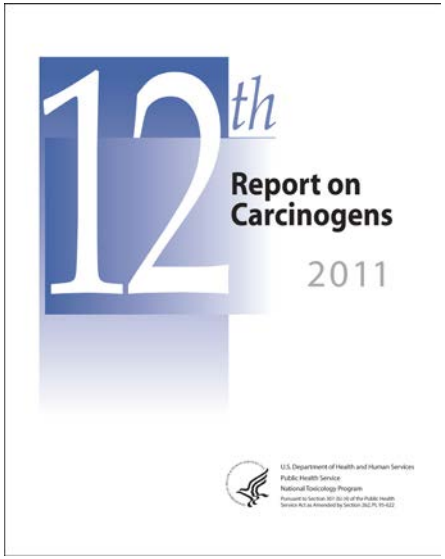
Report on Carcinogens (RoC)

- Congressionally mandated, science-based report
- Hazard identification document
  - Identifies agents, substances, mixtures, or exposure circumstances that may pose a cancer hazard for people in the United States
  - Lists “substances” as *known to be human carcinogens* or *reasonably anticipated to be human carcinogens* according to established RoC listing criteria
- Prepared by the NTP for the Secretary of the Department of Health and Human Services (HHS)
  - Preparation of the report is managed by the Office of the RoC within the Division of the NTP at the National Institute of Environmental Health Sciences
- 12th RoC published in June 2011



NTP Advisory Groups

- **NTP Executive Committee** – provides policy oversight to the NTP. Composed of the heads (or their designees) of nine federal participating agencies

Agency for Toxic Substances and Disease Registry / National Center for Environmental Health	National Cancer Institute
Consumer Product Safety Commission	National Institute of Environmental Health Sciences
Department of Defense	National Institute for Occupational Safety and Health
Environmental Protection Agency	Occupational Safety and Health Administration
Food and Drug Administration	

- **NTP Board of Scientific Counselors** – federally chartered advisory group that provides scientific oversight to the NTP. Members are appointed by the Secretary, HHS.
- **NTP Panels** – federally chartered, technical, scientific bodies established to provide the NTP expert scientific advice on targeted issues and independent peer review. Panels are convened as needed by the NTP (e.g., expert panel, peer-review panel)

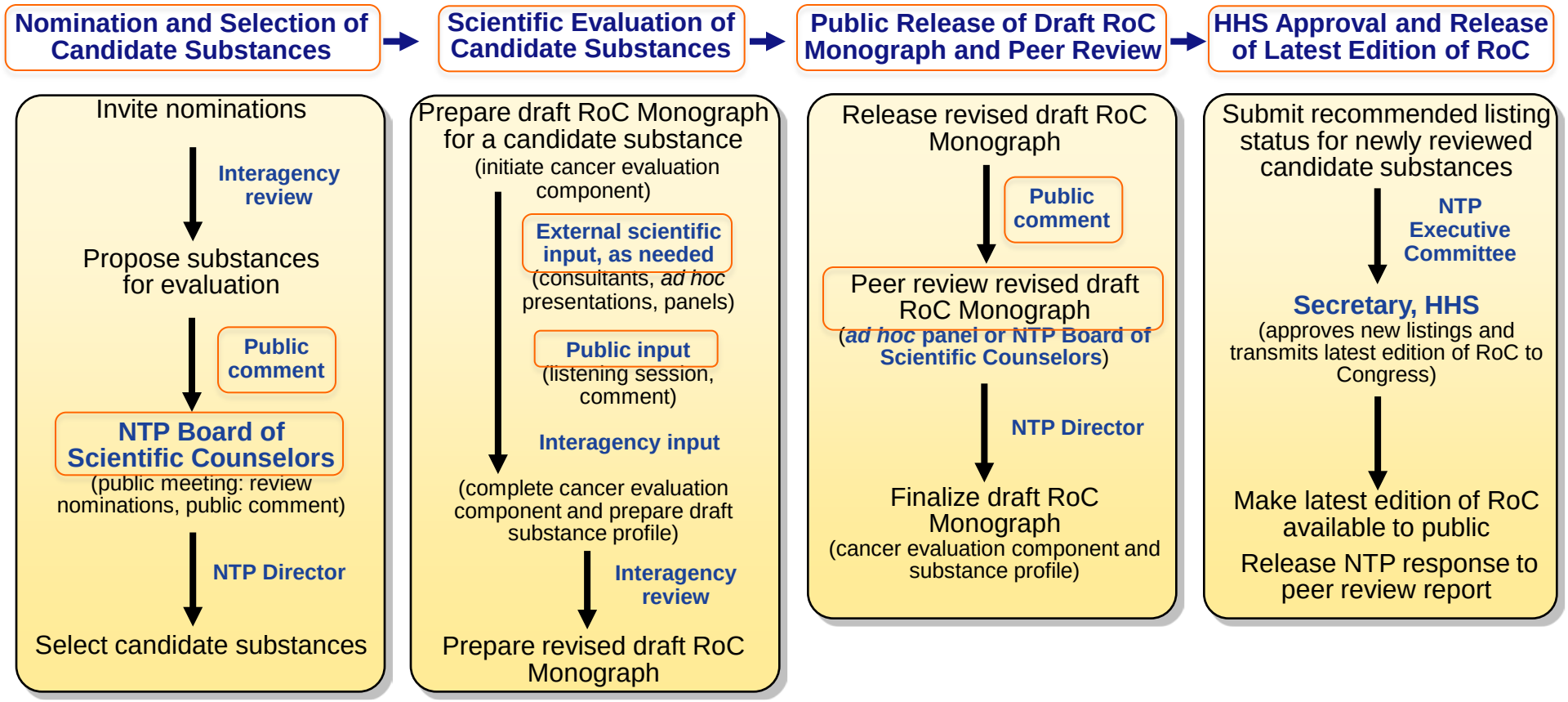
Concept Document

- Each substance proposed for review for the RoC will have a concept document
- Prepared as a draft for public comment and NTP Board of Scientific Counselor comment
- Draft concept:
  - Outlines the reason for a substance's review for the RoC
  - Lays out the proposed approach for development of the RoC monograph's cancer evaluation component for a substance
- Approach is guided by the nature, extent, and complexity of the scientific information on the substance
  - Is flexible and tailored to enable NTP to obtain external advice and address scientific issues for assessing a substance's carcinogenicity
  - May include external scientific input (e.g., expert panel, consultants), public input (e.g., listening session, comment), and/or interagency input
  - May vary among substances reviewed for the RoC

RoC Monograph

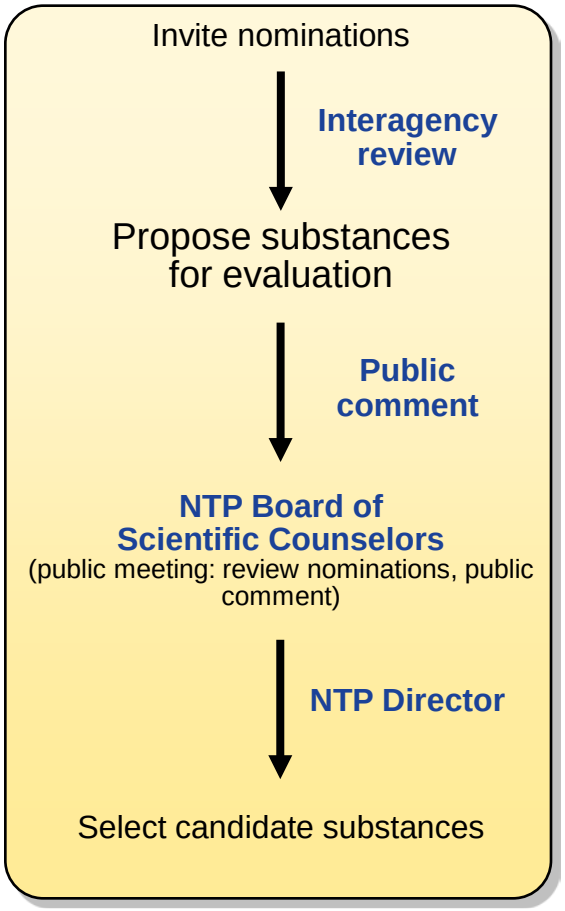
- Each candidate substance reviewed for the RoC will have a RoC Monograph with two parts:
  - Cancer evaluation component
  - Substance profile (final is included in the RoC)
- Prepared as a draft that undergoes public peer review
- Cancer evaluation component of the draft monograph
  - Reviews, assesses, and applies the RoC listing criteria to the relevant scientific information on the candidate substance
  - Recommends a listing status in the RoC for the candidate substance
- Substance profile of the draft monograph
  - Contains NTP's preliminary listing recommendation and summary of the supporting scientific evidence for carcinogenicity
  - Contains information about production, use, exposure, and current regulations for the candidate substance

Proposed RoC Review Process



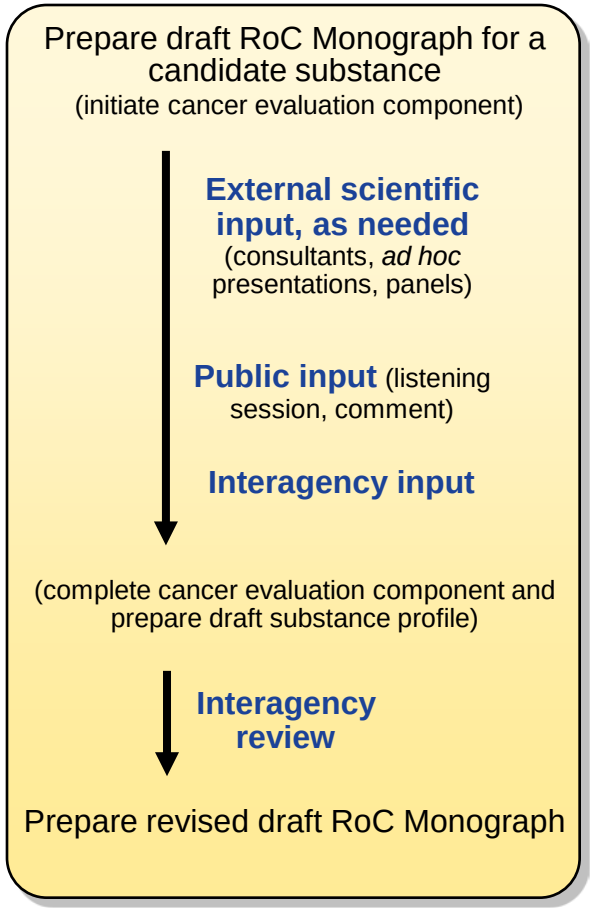
Key
HHS = Department of Health and Human Services
NTP = National Toxicology Program
RoC = Report on Carcinogens

Part 1: Nomination and Selection of Candidate Substances



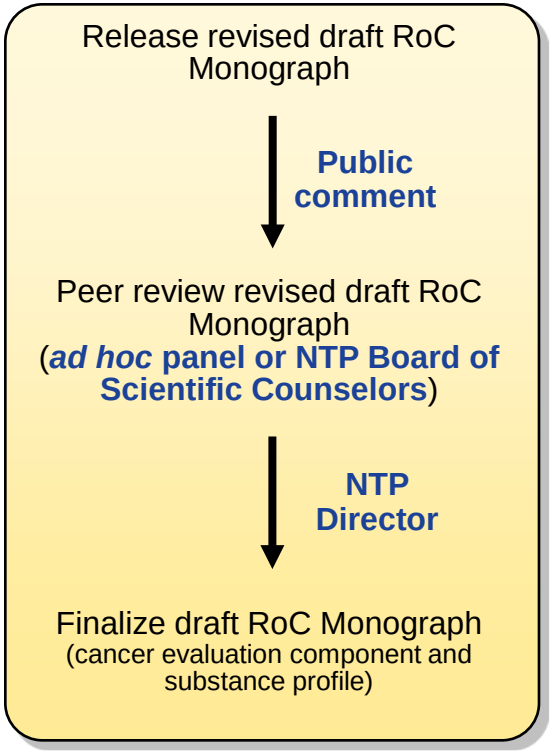
- Nomination may seek to (1) list a new substance in the RoC, (2) reclassify the listing status of a listed substance, or (3) remove a substance already listed.
- NTP develops a draft concept document for each substance proposed for evaluation
- NTP solicits public comment on the draft concept and presents it to the NTP Board of Scientific Counselors at a public meeting
- NTP considers the public and Board of Scientific Counselor comments and the NTP Director makes the final determination whether to add a substance to the list of candidate substances for RoC review
  - Substances are approved for review, but not for any specific RoC edition
- NTP finalizes concepts for approved candidate substances and posts them to RoC website

Part 2: Scientific Evaluation of Candidate Substances



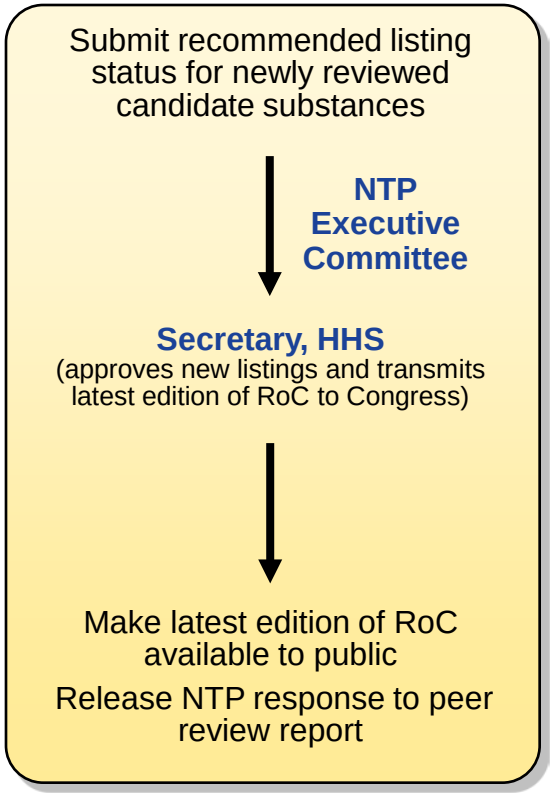
- NTP prepares a draft RoC Monograph for each candidate substance
- NTP initiates preparation of the cancer evaluation component of the draft monograph
  - Follows approach to obtain external scientific, public, and/or interagency inputs as outlined in final concept document
- NTP completes the draft cancer evaluation component, prepares the draft substance profile, and compiles them to form the draft RoC Monograph
- NTP requests comment on the draft RoC Monograph from its partner agencies, considers input, and as appropriate, prepares a revised draft

Part 3: Public Release of Draft RoC Monograph and Peer Review



- NTP releases the revised draft RoC Monograph for public comment and peer review
- NTP convenes an external scientific group (*ad hoc* expert panel or NTP Board of Scientific Counselors) to peer review draft RoC Monograph
- Peer review charge:
  - (1) Comment on cancer evaluation component, specifically, whether it is technically correct and clearly stated, whether the NTP has objectively presented and assessed the scientific information, and whether the scientific evidence is adequate for applying the listing criteria
  - (2) Comment on the substance profile, specifically, whether the scientific justification supports the NTP's preliminary policy decision on the listing status of the candidate substance in the RoC
- NTP considers the peer-review comments and finalizes the draft RoC Monograph

Part 4: HHS Approval and Release of Latest Edition of RoC



- Biennially, NTP submits newly reviewed candidate substances with their recommended listing status to
  - NTP Executive Committee
  - Secretary, HHS
- Substance profiles for new listings approved by the Secretary are added to the RoC
- NTP prepares next RoC edition in electronic format
- RoC is transmitted to the Congress, published on RoC website, and availability announced to public
  - NTP periodically publishes RoC in printed and electronic formats
- NTP posts its response to the peer-review report on the draft RoC Monograph on the RoC website